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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/820,518	04/08/2004	Arnold R. Leiboff	461.1012	8311

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EXAMINER

MARCETICH, ADAM M

ART UNIT	PAPER NUMBER
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3761

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/09/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

**Office Action Summary**

Application No.

10/820,518

Applicant(s)

LEIBOFF, ARNOLD R.

Examiner

Adam Marcetich

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 8 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-46 is/are pending in the application.
- 4a) Of the above claim(s) 12-46 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-5 and 7-11 is/are rejected.
- 7) ☒ Claim(s) 6 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Election/Restrictions*

1. Claims 12-46 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to nonelected inventions, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 30 January 2007. Claims 1-11 read on the elected invention.

### *Claim Rejections - 35 USC § 103*

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

3. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

4. Claims 1, 2 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eld (US Patent 5,545,141) in view of Klingenstein (US Patent 6,149,581).

5. Regarding claim 1, Eld discloses a method of implanting a tube into the GI (gastrointestinal) system using a guidewire with a removable needle which is inserted into the GI tract, manipulated into position (column 2, lines 46-57 through column 3, lines 1-3), passing a filament through the abdominal wall (lines 53-56), withdrawing the device to pull the filament out of the patient and optionally attaching a tube, pulling on the filament to move the tube back into the patient (column 3, lines 4-15), and fixing the tube in place (column 6, lines 9-24, especially lines 22-24).

Eld lacks the steps of inserting a guidewire into the colon through the anus and rectum and attaching a drainage tube to the filament. Klingenstein discloses a method for fixing a tube within the colon, for the purpose of treating colonic distention and Ogilvie's syndrome (column 2, lines 38-52). Klingenstein discloses inserting an endoscopic probe through the anus and rectum into the cecum (column 2, lines 1-31), and attaching a tube having apertures to the probe via filaments (column 9, lines 30-67 through column 10, lines 1-15, especially lines 41-46), and fixing the tube in place (column 4, lines 43-58, especially lines 43-45). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the invention of Eld as discussed with the insertion and attaching steps of Klingenstein in order to provide a method of treating Ogilvie's syndrome as called for by Klingenstein.

6. Regarding claim 2, Eld discloses threading a strand through a channel in the probe (column 6, lines 9-24 and Fig. 2A, element 72).

7. Regarding claim 11, Eld discloses the step of engaging a filament with a guidewire, withdrawing the guidewire through the GI tract to pull a filament through the

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patient's mouth and optionally attaching a tube (column 3, lines 4-15). Eld solves the problem of pulling a filament through an end of the GI tract. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to clamp or otherwise restrain one end of the filament to prevent its movement, and to apply the method of Eld to pulling a filament through a patient's colon and anus.

8. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Eld and Klingenstein in view of Amplatz et al. (US Patent 4,991,602) and Scribner et al. (US Patent 5,830,125). Eld discloses a needle having a flat side (Fig. 2A, element 50 and column 4, lines 25-42), and passing this needle through the GI tract wall as discussed in paragraph 5 above. Eld lacks a guidewire with a bulbous enlargement, and passing a needle with threaded filament through the channel.

Amplatz solves the problem of inserting a guidewire into a hollow organ (column 2, lines 18-32) and discloses using a guide wire with a bulbous enlargement (Figs. 2 and 3, element 24) for the purpose of improving safety (column 5, lines 4-25). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the invention of Eld as discussed with the bulbous enlargement of Amplatz in order to prevent perforating any region of the GI tract during an implanting procedure.

Scribner solves the problem of suturing tissue together (abstract). Scribner discloses a step of passing a needle threaded with a suture through a guidewire (column 16, lines 48-67 through column 17, lines 1-7 and Figs. 7C and 7D, elements

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230, 280 and 300). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the invention of Eld with the needle passing step of Scribner in order to efficiently introduce a threaded needle into a surgical site.

9. Claims 4, 5, 9 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Eld and Klingenstein in view of Gill (US Patent 5,851,195).

10. Regarding claim 4, Eld lacks locating a guidewire in the cecum. Klingenstein discloses locating a guidewire in the cecum as discussed in paragraph 5 above. With respect to motivation, see paragraph 5 above. Eld and Klingenstein lack the step of passing a filament through the colon wall and into engagement with a guidewire. Gill discloses passing a filament through the intestinal wall and abdomen, which is attached to the implant (Figs. 7 and 8, element 56 and column 3, lines 34-51). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the methods of Eld and Klingenstein as discussed with the passing step of Gill in order to provide a means of pulling the implant through the GI tract wall.

11. Regarding claim 5, Examiner takes Official Notice that attaching a cord or filament to a tube by passing it through a tip and/or tying it around the tube is well-known to those knowledgeable in the art. For example, a "hitch" is a type of knot used to secure rope or cord to a cylindrical object (see online encyclopedia reference).

12. Regarding claims 9 and 10, Eld and Klingenstein disclose a colonic implant as discussed. Eld and Klingenstein lack the step of passing a portion of the tube through

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the colon and abdominal wall, and securing the tube to the patient's skin. Gill solves the problem of implanting an access catheter for the jejunum, and provides a method of implanting it (abstract). Gill further discloses passing a portion of the tube through the walls of the intestine and abdomen (Figs. 7 and 8, element 56 and column 3, lines 34-51), and securing the implant tube to the patient's skin with a retention member (Figs. 7 and 8, element 58 and column 3, lines 59-67 through column 4, lines 1-6). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the invention of Eld and Klingenstein with the passing and fixing steps of Gill in order to provide secure access to the patient's GI tract as called for by Gill.

13. Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Eld and Klingenstein in view of Cragg (US Patent 6,315,789). Eld discloses the step of passing the filament through the abdominal wall as discussed above for claim 1 in paragraph 5 above. Eld and Klingenstein lack the step of attaching a portion of the filament to the patient's skin. Cragg solves the problem of implanting a tube through a patient's skin (abstract), and discloses a method of attaching a percutaneous device using a suture (column 4, lines 29-49). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the invention of Eld and Klingenstein with the attaching step of Cragg in order to secure the implant more solidly. Examiner takes official notice that the steps of cutting the filament is well known to those skilled in the art.

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14. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Eld and Klingenstein in view of Cosmetto et al. (US Patent 5,127,412). Eld and Klingenstein disclose the method of implanting a drainage tube as discussed in paragraph 5 above. Eld and Klingenstein lack the step of fixing the tube in place by passing a filament through the abdominal wall, spooling the filament and affixing the spool to the abdominal surface. Cosmetto solves the problem of affixing a device to the abdomen (column 6, lines 51-56 and Fig. 14), and discloses passing a filament through the abdominal wall, spooling the filament and attaching the spool to the abdominal wall (column 4, lines 59-68 through column 5, lines 1-30, especially lines 1-8 and Figs. 2-6). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to combine the methods of Eld and Klingenstein as discussed with the spooling step of Cosmetto in order to affix a device to the abdominal wall as called for by Cosmetto.

#### ***Allowable Subject Matter***

15. Claim 6 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

#### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Adam Marcetich whose telephone number is 571-272-



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2590. The examiner can normally be reached on 8:30am to 5:00pm Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tatyana Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Adam Marcetich  
Examiner  
Art Unit 3761



AMM 3/20/07

TATYANA ZALUKAEVA  
SUPERVISORY PRIMARY EXAMINER

